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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,444	11/27/2001	Elizabeth Esther Mary Bates	DX0669KB	1324

EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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PATENT DEPARTMENT
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Please find below and/or attached an Office communication concerning this application or proceeding.

ACTION: Office Action
DATE DUE: Jan. 28, 2005

PTO-90C (Rev. 10/03)

Office Action Summary	Application No. 09/994,444	Applicant(s) BATES ET AL
	Examiner G. R. Ewoldt, Ph.D.	Art Unit 1644

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *09 August 2004*.

2a)☐ This action is FINAL. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *20-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a)☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

mailed 08/05/04

DETAILED ACTION

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed 8/09/04 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendments and remarks filed 8/09/04 have been entered.

2. Claims 20-27 are pending and being acted upon.

3. Applicant's identification of support in the Sequence List has obviated the previous rejections of Claims 21 and 23 under the first paragraph of 35 U.S.C. 112 for the introduction of new matter.

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 20-27 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

As set forth previously, the instant claims are drawn to a polynucleotide encoding the polypeptide referred to as A07C03 (SEQ ID NO:8). The specification asserts at page 18 that the claimed polynucleotides are useful "to isolate genes from other species". The protein encoded by the claimed polynucleotide is asserted to be useful "for generating antibodies." The antibodies could then be useful for screening expression libraries. Clearly, what the specification discloses is that the claimed invention is useful essentially for studying itself. Said study is not considered to be a specific and substantial asserted utility or a well-established utility. At page 59, the specification discloses that the claimed "DNA or RNA may be used as a component in a forensic assay," however, no specific assays are disclosed. Again, this use is not considered to be a specific and substantial asserted utility or a well-established utility. Therapeutically, the specification discloses that the protein encoded by the claimed polynucleotide "may be useful in the treatment of conditions associated with abnormal physiology or development, including abnormal proliferation, e.g., cancerous

conditions, or degenerative conditions." However, no correlation or connection between the polynucleotides of the instant claims, nor the proteins they might encode, with any "abnormal physiology" or conditions is established. Again, this use is not considered to be a specific and substantial asserted utility or a well-established utility.

Applicant's arguments, filed 8/09/04, have been fully considered but they are not persuasive. Applicant again argues that A07C03 is dendritic cell and monocyte specific, thus, the polynucleotides can be used as markers for dendritic cells and dendritic cell precursors.

It remains the Examiner's position that the specification does not provide a substantial asserted utility or a well-established utility for the polynucleotide of the instant claims. Note that little is disclosed about the polynucleotide other than it appears to one of multiple splice variants that are dendritic cell/monocyte/dendritic cell precursor specific. Accordingly, the claimed polynucleotide cannot even be considered a marker for any particular type or developmental stage of the various known dendritic cells/monocytes/dendritic cell precursors. Also note that the specification does not even actually reveal how the polynucleotide was isolated. While not required, such a disclosure might have been helpful in establishing utility.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 20-27 stand also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a credible utility, for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

See Applicant's arguments and the Examiner's response of part 4 above.

the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

10/26/04

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